IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Before the Board of Patent Appeals and Interferences

In re: Application of RAY, et al.

Application No.:	09/222,123	Examiner:	Cross, L.
Date filed:	December 29, 1998	Group:	1743

For: REMOTE SITE URINE COLLECTION DEVICE AND METHOD OF USE

CERTIFICATE UNDER 37 CFR 1.8(a)

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Reg. No. 42,730

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APPELLANT'S BRIEF ON APPEAL

Mail Stop Appeal
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Sir:

Appellant having filed a timely Notice of Appeal in the above-identified patent application, hereby submits this brief.

I. REAL PARTY IN INTEREST

The real party in interest is the assignee, Flexsite Diagnostics, Inc.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

Claims 1-20 were included in the originally filed application. In the amendment filed July 11, 2000, claims 13-18 were cancelled, claims 1, 5-7, 12, and 19 were revised, and new claim 21 was added. Pursuant to the Request for Continued Examination filed February 16, 2001, an amendment filed January 23, 2001 was entered revising claims 1-7, 19, and 20. In the amendment filed September 13, 2001, claims 1-3, 19, and 24 were revised and new claims 27-42 were added. Pursuant to the Request for Continued Examination filed April 26, 2002, an amendment filed March 5, 2002 was entered canceling claims 1-12, 22, 23, and 28 and amending claims 19, 25, 27, and 29. No claims were cancelled, revised, or added in the response filed February 3, 2003, leaving claims 19, 21, 24-27, and 29-42 pending in the application.

The office action mailed April 22, 2003 (the "Office Action") indicated that claims 1-21, 24-27, and 29-42 were pending in the application. Appellants believe this to be an error, although the Office Action does not expressly indicate that appellant's February 3, 2003 amendment was entered. In any case, all pending claims stood rejected under 35 U.S.C. §103. This appeal is taken with respect to pending claims 19, 21, 24-27, and 29-42, which are set forth in Appendix A hereto.

IV. STATUS OF AMENDMENTS

No amendments were filed by the appellant subsequent to issuance of the Office Action.

V. SUMMARY OF THE INVENTION

As illustrated in Figs. 1-3, the claimed invention relates to a sample collection device 10 in the form of a strip 12 having a handle end 13 and a collection end 14. The collection end 14 of the device 10 has at least one collection pad 11 made of a sponge-like material (specification page 10, line 10). The sponge-like material can be made of polyvinyl alcohol (specification page 10, line 16). It may also include a plurality of pores (e.g., sized from about 0.01 to about 1.2 mm (specification page 10, line 22)). The sponge-like material can be one having a dry density of between about 0.049 and about 0.1 gram per cubic centimeter (specification page 10, line 21). The collection pad 11 can have applied thereon a reagent which facilitates the collection, separation, storage, transport, preservation, recovery, or analysis of the sample (e.g., bovine serum albumin) (specification page 11, lines 12-18), and can be substantially non-reactive for purposes of providing a rapid, on-site diagnostic test (specification page 10, lines 7-9). As described in the specification at pages 12, line 16-22, the collection pad 11 can also have absorbed therein the biological sample (e.g., urine) containing the analyte (e.g., albumin derived from urine; see Example 1).

The device also includes a means for facilitating removal of at least a portion of the collection pad from the strip 12 (specification pages 12, line 1-2) to recover the analyte for detection or measurement by laboratory analysis. The means can take the form of one or more apertures 15 formed through the collection end 14 of the strip 10. As described in the paragraph bridging pages 9 and 10, the strip 12 can be made of a polymer (e.g., polystyrene) and be rigid enough to prevent drooping or bending of the strip 12 during manipulation by a user of the device.

As described in the specification at page 17, lines 3-9, the sample collection device 10 may form part of a kit that may also include an information card for providing information about the

patient, a urine collection cup for collecting a urine sample, and/or a packaging means for transporting the device.

VI. ISSUES ON APPEAL

A. Whether claims 19, 21, 24-27 and 29-42 are unpatentable under 35 U.S.C. 103(a) over U.S. Patent No. 5,609,160 (Bahl) in view of U.S. Patent No. 5,728, 350 (Kinoshita).

B. Whether claim 20 is unpatentable under 35 U.S.C. 103(a) over Bahl in view of Kinoshita and further in view of U.S. Patent No. 5,976,895 to Cipkowski (Cipkowski).

VII. GROUPING OF CLAIMS

No special grouping of the claims is requested.

VIII. ARGUMENT

Issues A and B above are considered together in the following argument as both rely on Bahl and Kinoshita.

A. Bahl and Kinoshita are not properly combinable under 35 U.S.C. § 103

In the Office Action, claims 19, 21, 24-27 and 29-42 were rejected under 35 U.S.C. 103 (a) as being unpatentable over Bahl in view of Kinoshita. More specifically, the Office Action stated:

> Bahl et al. '160 teach a fluid sample collection device comprising a plastic frame having a handle end (30, 40) and a collection end. The plastic frame is rigid enough to be held by the user, as in claims 25 and 26. The device contains an absorbent cotton (cellulosic) pad (50) for collecting the sample. There are openings (32, 42) through the collection end of the device such that the absorbent pad is exposed and capable of collecting the sample. The device also contains an additional opening (28), which allows the oral sample to be extracted during centrifugation.

The Office Action points out that Bahl fails to teach polyvinyl alcohol as the absorbent material, as recited in claims 19 and 27-32, but relies on Kinoshita to provide the motivation to combine the device of Bahl with a sample receiving part made of polyvinyl alcohol, to arrive at the claimed invention. More particularly, as stated in the Office Action:

> Kinoshita et al '350 teaches a test kit having an absorbent sample receiving part on a support material. The sample receiving part is made of water absorbing fibrous material, such as polyvinyl alcohol. See col. 3, lines 46-63. ... It would have been obvious to one of ordinary skill in the art to use the polyvinyl alcohol material disclosed by Kinoshita et al. '350 in the Bahl et al. device to provide enhanced absorbency for the sample.

As appellant noted in the February 3, 2003 Response, this rejection is incorrect because the teachings of Bahl and Kinoshita are not properly combinable for the purposes of 35 USC 103. In particular, (a) neither Bahl or Kinoshita suggest the desirability of combining their teachings, and (b) modification of the Bahl device with the polyvinyl alcohol material disclosed by Kinoshita would render the Bahl device unsatisfactory for its intended purpose.

Citing In re Mills (916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990)), MPEP (8th Edition) 2143 provides "[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." The Bahl device is designed to enable detection of antibodies, antigens, viruses and the like contained in oral fluid samples, subsequent to in-home collection of such samples, and mailing of same to a laboratory facility. Upon arrival of the device at the laboratory, the liquid sample, bathed in a preservative, is recovered from the device by centrifugation within its own mailer. Bahl Col. 1, lines 35-56. During centrifugation, a seal (63) in the mailer (shown in Bahl Figs. 1, 3, 4, 11, 13) breaks open, allowing for recovery and subsequent testing of the fluid sample which is dispersed in the preservative. (See Bahl Col. 2, lines 56-62).

It is apparent from the foregoing that the fluid-absorbing material used for the sample collection pad in the Bahl device must be well-suited both for the collection of the liquid sample from the subject, and for the centrifugation step required for recovery of the sample from the collection pad. The Office Action contends that the motivation to combine the device of Bahl with the polyvinyl vinyl alcohol material disclosed in Kinoshita would have been to "provide enhanced absorbency for the sample." Inadequate absorbency, however, is clearly not a problem in Bahl's device.

For example, Bahl does not indicate that obtaining a sufficient volume of the sample is problematic. In this regard, Bahl (Col 3, line 51-54) states that the pad made of pure 100% cotton "will hold between 0.75 ml and 1.2 ml of the oral fluid sample." Nowhere does Bahl indicate that this volume is insufficient. Moreover, Bahl's device includes an indicator that changes color "only when sufficient oral fluid has been absorbed by the pad as is required for the analytical procedures." Bahl Col. 3, lines 45-49. Thus, Bahl does not suggest the desirability of modifying its collection pad.

In the Office Action, the examiner addressed the foregoing argument by admitting that Bahl does not explicitly recite that its collection pad may be modified, but countering that because Bahl's device includes and indicator for determining whether enough sample has been taken up suggests that absorbency of the pad is important. Appellant, however, had never argued that absorbency was not important to the functioning of the Bahl device. Rather, appellant had argued that because Bahl indicates that its disclosed absorbent cotton collection pad is sufficient to collect a required volume of sample, Bahl does not provide motivation to substitute this cotton material with a more absorbent material (e.g., sponge-like polyvinyl alcohol). The examiner did not address this point.

In the February 3, 2003 Response, appellant also argued that even if the Bahl device were modified to include Kinoshita's polyvinyl alcohol material, the resulting device would be unsatisfactory for its intended purpose. In particular, substituting the polyvinyl alcohol material disclosed by Kinoshita for the 100% cotton pad of the Bahl device would hinder collection of an analyte contained therein. Citing In re Gordon (733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)), MPEP (8th Edition) 2143 provides "[i]f [the] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." Bahl's device and Kinoshita's apparatus differ markedly in their operation. Bahl's device is a sample collection device in which a sample is collected and later removed for analysis. The device itself does not produce test results. In comparison, Kinoshita's apparatus is a test strip which does produce test results. Because of these differences, the components in Bahl's device operate differently from those in Kinoshita's apparatus. More specifically, Bahl's device is designed to both collect and release a sample, while Kinoshita's apparatus is designed only to collect a sample.

Accordingly, as the Office Action notes, "Kinoshita et al '350 teach that polyvinyl alcohol materials are preferred because they have an excellent effect of thickening the liquid sample when the sample is absorbed. Thus, sample is retained more firmly and is difficult to remove. (col. 4, lines 1-5)." If the substitution suggested by the examiner were employed, appellant suspects removal of the sample by the centrifugation step taught by Bahl would be impracticable or perhaps impossible. For these reasons, Bahl and Kinoshita are not properly combinable for the purposes of 35 USC 103.

In the Office Action, the examiner addressed the foregoing by stating that "Applicants did not provide any reasoning to support such a conclusion." The examiner further stated "The fact

that Kinoshita et al performs analytical tests on the collected sample and Bahl extracts the sample to perform analytical tests is irrelevant to whether the collection pad if Kinoshita et al would allow for centrifugation/extraction of the sample." Appellant respectfully disagrees with these statements. First, appellant did provide reasoning to support the argument. See page 5 of the February 3, 2003 Response. Second, the differences in operation of the Bahl device versus the Kinoshita device are relevant to the selection of a collection pad as a collection pad that is capable of releasing a liquid sample upon centrifugation is necessary for the proper operation of the Bahl device (wherein a sample removed from the device is analyzed) whereas a collection pad that firmly retains a sample is desirable for the proper operation of the Kinoshita device (wherein the analyte is analyzed on the device itself).

IX. CONCLUSION

As a consequence, appellant requests reversal of the final rejection in the instant patent application.

Respectfully submitted,

Date: September 22, 2003

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APPENDIX A

Claims of Patent Application Serial No. 09/222,123

19. A kit comprising:

a sample collection device comprising a strip having a handle end and a collection end, said collection end having a collection pad, the collection pad being a sponge-like material made of polyvinyl alcohol,

wherein the device includes a means for facilitating removal of at least a portion of the collection pad from the strip to recover the analyte for detection or measurement by laboratory analysis; and

an information card for providing information about the patient.

20. The kit of claim 19 wherein said kit further comprises a urine collection cup for collecting a urine sample.

21. The kit of claim 19, wherein the means for removing at least a portion of the collection pad comprises an aperture formed through the collection end of the strip.

24. The kit of claim 19 wherein said kit further comprises packaging means for transporting the device.

25. The kit of claim 19, wherein said strip is made of a polymer and is rigid enough to prevent drooping or bending of the strip during manipulation by a user of the device.

26. The device of claim 25, wherein said polymer is polystyrene.

27. A device for laboratory analysis of an analyte, the device comprising:

a strip having a handle end and a collection end, the collection end having attached thereon a collection pad for collecting and drying a liquid biological sample containing the analyte,

wherein the collection pad consists essentially of a sponge-like material made of polyvinyl alcohol.

29. The device of claim 27, wherein the collection pad consists of the sponge-like material.

30. The device of claim 27, wherein the sponge-like material comprises a plurality of pores.

31. The device of claim 30, wherein the pores are sized from about 0.01 to about 1.2 mm.

32. The device of claim 27, wherein the sponge-like material has a dry density of between about 0.049 and about 0.1 gram per cubic centimeter.

33. The device of claim 27, wherein the device further comprises a means for facilitating removal of at least a portion of the collection pad from the strip to recover the analyte for detection or measurement by laboratory analysis.

34. The device of claim 33, wherein the means for facilitating removal of at least a portion of the collection pad comprises an aperture formed through the collection end of the strip.

35. The device of claim 27, wherein the collection pad has applied thereon a reagent which facilitates the collection, separation, storage, transport, preservation, recovery, or analysis of the sample.

36. The device of claim 35, wherein the reagent is bovine serum albumin.

37. The device of claim 27, wherein the collection pad is substantially non-reactive for purposes of providing a rapid, on-site diagnostic test.

38. The device of claim 27, wherein the device comprises a plurality of collection pads.

39. The device of claim 38, wherein the device comprises a plurality of apertures formed through the collection end of the strip.

40. The device of claim 27, wherein the collection pad has absorbed therein the biological sample containing the analyte.

41. The device of claim 40, wherein the biological sample comprises urine.

42. The device of claim 41, wherein the biological sample comprises albumin derived from urine.